

**REMARKS**

The Office Action dated May 6, 2009, addresses claims 31, 34-37, 40-42 and 60-63 rejecting all claims under 35 U.S.C. § 103(a). Claims 31, 34-35 and 60-63 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nobles (U.S. Publication No. 2002/0045908, which issued as U.S. Patent No. 6,562,052, "Nobles") in view of Ginn et al. (U.S. Patent No. 6,702,835, "Ginn"). Claim 36 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Nobles in view of Ginn and further in view of Sawyer (U.S. Patent No. 5,749,895, "Sawyer"). Claim 37, 40 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nobles in view of Ginn and further in view of Das (U.S. Patent No. 5,334,217, "Das"). Claim 42 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Nobles in view of Ginn and Das and further in view of Sawyer.

Applicants amend claims 31 and 37 to clarify the subject matter of the claims. No new matter has been introduced by this Amendment.

For all of the following reasons, Applicants respectfully request reconsideration and early allowance of the claims as currently amended.

**Rejection of claims under 35 U.S.C. § 103(a)**

Applicants respectfully traverse the rejection of claims 31, 34-37, 40-42 and 60-63 under 35 U.S.C. § 103(a) as being unpatentable over Nobles in view of one or more of the Ginn, Das and Sawyer references. Applicants respectfully submit that the proposed combination of the Noble, Ginn, Das and Sawyer references fail to support a *prima facie* case of obviousness under 35 U.S.C. § 103. As set forth in the MPEP, to

establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the Office bears the burden of establishing each of three requirements. First, the references must teach or suggest each and every element and limitation recited in the claims. *See M.P.E.P. § 2143.03.* Second, the Office must establish that some suggestion or motivation exists, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references to achieve the presently claimed invention. *See M.P.E.P. § 2143.01.* Third, the Office must establish a reasonable expectation of success for the proposed combination. *See M.P.E.P. § 2143.02.* In the present case, Applicants assert that independent claims 31 and 37 recite at least one limitation that is not taught, disclosed or suggested by Noble, Ginn, Das and Sawyer, either alone or in combination.

Independent claims 31 and 37, as amended, recite at least the limitation "introducing a hole through said septum primum from the right atrial side of the septum primum to the left atrial side of the septum primum, and simultaneously applying pressure to said second free end portion in contact with the tissue of said septum primum to minimize movement of said septum primum," which is not taught, disclosed or suggested by Nobles. The Examiner equates the first flexible member as recited in claims 31 and 37 to the suture clasp arms 28, 30 of Nobles. *See Office Action at Page 2.* Applicants respectfully point out that although the proximal sides of the suture clasp arms 28, 30 are initially positioned in contact with the tissue wall 22, as shown in FIG. 4B of Nobles, nowhere does Nobles disclose, teach or suggest applying pressure to the suture clasp arms 28, 30 to limit the movement of the tissue as needles 136 penetrate

the tissue. Applicants assert that the suture clasps 28, 30 are simply configured to mount an end portion of a suture 40, which are subsequently engaged by needles 136, and therefore, the suture clasps are not required to remain in immediate proximity to the tissue wall 22 as the needles penetrate the tissue. Nowhere does Nobles provide any teaching or suggestion for using the suture clasp arm 28, 30 to manually limit the movement of the tissue as needles 136 introduce one or more through-holes 248 in the tissue. In fact, the suture clasp arms 28, 30 are retracted from the tissue wall 22 as needles 136 penetrate the tissue, as demonstrated in FIG. 36 of Nobles (reproduced on the right), and therefore, cannot provide the function of maintaining tissue stability as the needles penetrate the tissue.

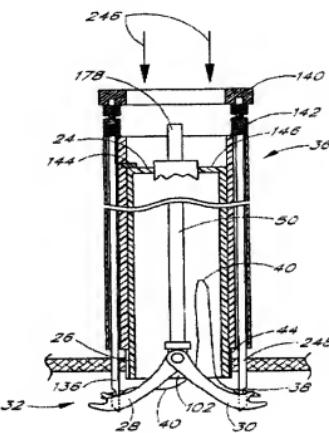


FIG. 36

Ginn, Das and Sawyer fail to overcome this deficiency of Nobles. The Examiner has cited Ginn, Das and Sawyer only with regards to the direction of tissue penetration, hexagonal-shaped septal defect occluder and tissue welding apparatus, respectively. Ginn, Das and Sawyer do not disclose, teach or suggest any flexible member for stabilizing a tissue while introducing a hole therethrough. Therefore, Ginn, Das and Sawyer fail to cure the above-mentioned deficiency of Nobles.

For at least the above reason, Applicants respectfully submit that independent claims 31 and 37, as amended, is patentable over Nobles in view of Ginn. Claims 34, 35 and 36 depend from claim 31, and claims 40-42 and 60-63 depend from claim 37, and therefore, are patentable over Nobles, Ginn, Das and Sawyer for at least the same reasons as claims 31 and 37, respectively. Applicants respectfully request that the rejection of claims 31, 34-37, 40-42 and 60-63 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

It is respectfully submitted that the remarks presented here clarify the claims for the purposes of appeal, entry of which is earnestly solicited.

**CONCLUSION**

In view of the foregoing remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the claims as amended.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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